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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/046,313	01/16/2002	Akihiro Yokoyama	218203US0	2679

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EXAMINER	
SPIEGLER, ALEXANDER H	

ART UNIT	PAPER NUMBER
1637	

DATE MAILED: 06/17/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/046,313	YOKOYAMA ET AL.	
	Examiner	Art Unit	
	Alexander H. Spiegler	1637	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *18 February 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-8* is/are pending in the application.

4a) Of the above claim(s) *1,2,4 and 8* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *3 and 5-7* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *16 January 2002* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *5/2/02 & 8/2/02*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Applicants' election with traverse of Group III (Claims 3 and 5-7) and SEQ ID NOS: 4 and 23, in Applicants' response filed on February 18, 2004 is acknowledged. It is noted that although Claim 8 was included in Group III in the restriction, Claim 8 is drawn to detecting Salmonella gene *stn* (see page 9, lines 11-12), whereas Group III is drawn to detection amplification and detection of Salmonella gene *invA*. Accordingly, because Claim 8 is not drawn to the elected invention (methods for amplifying and detecting Salmonella gene *invA*), Claim 8 is withdrawn from consideration. See 37 CFR 1.142(b) and MPEP § 821.

Applicants' Arguments

Applicants' argue:

1) Because SEQ ID NOS: 1-12 bind to the same gene, they share structural and functional similarities, SEQ ID NOS: 13-18 bind to the same gene and share structural and functional similarities, SEQ ID NOS: 19-23 contain sequences homologous to portions of the same gene, and SEQ ID NOS: 24-27 contain sequences homologous to portions of the same gene, there is no serious burden to examine them together.

2) If the invention is so narrowed, Applicants cannot adequately claim the invention, which is to provide oligonucleotides capable of complementarily binding to intramolecular regions of Salmonella gene *invA* mRNA and the Salmonella gene *stn* mRNA and the related processes using these oligonucleotides.

3) The Examiner should search all of the sequences because they are classified in the same class, SEQ ID NOS: 19-23 have the same initial 28 bases, and SEQ ID NOS: 24-27 also have the same initial 28 bases.

4) The product and process claims should be examined together, since the Office has not shown a serious search burden.

Response to Applicants' Arguments

Applicants' arguments have been considered, but are not persuasive for the following reasons:

1) Each of the groups of sequences (SEQ ID NO: 1-12, 13-18, 19-23 and 24-27) are all structurally and functionally distinct because they each have different structures (as evidenced by their different SEQ ID NOS), and they each have different functions (e.g., binding to different portions of either Salmonella gene *stn* or *invA*, or amplifying different regions of either Salmonella gene *stn* or *invA*). Accordingly, because each SEQ ID NO differs in structure and function, they are patentably distinct, and a serious search burden exists, as each sequence individually must be searched.

2) Given the restriction requirement, Applicants can still claim the invention, as the claims and specification clearly indicate that a single primer is used from SEQ ID NOS: 1-12 and single primer is used from SEQ ID NOS: 19-23. This is evidenced, for example, by the recitation of "any one of the sequences listed as SEQ ID NOS: 1-12 and...any one of the sequences listed as SEQ ID NOS: 19-23" as recited in Claim 3.

3) As stated above, each sequence differs structurally and functionally from one another, and each would require a separate search, and therefore, each sequence is patentably distinct.

With respect to sequences having the same initial 28 bases, these sequences are still structurally and functionally distinct, since they have different structures (viewed in their entirety) and bind to or amplify different sequences. Each of these sequences still would require a different search. In the restriction requirement, the following statement was made: "Should applicant traverse on the ground that the nucleic acids are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case." Since Applicants have not shown such evidence, it is assumed that these sequences are patentably distinct, and restriction is proper.

4) Restriction of related inventions is proper if it can be shown that the inventions have a different classification, or have acquired a separate status in the art or have a different field of search (see MPEP 808.02). The products and the methods of using products have acquired a separate status in the art as recognized by their different classification (see restriction requirement). In addition, the oligonucleotides of Group I, for example, can be used in a materially different method than that of Group 3, such as in a hybridization assay using an oligonucleotide array for simultaneous detection of different bacteria, or in another method such as in a method for diagnosing. Furthermore, it is maintained that each of the inventions are distinct for the reasons discussed in the previous Office action.

Accordingly, for these reasons, and those of record, the restriction requirement is deemed proper, and is made final.

Status of the Application

2. Claims 1-8 are pending, Claims 3 and 5-7 are rejected herein, and Claims 1-2, 4 and 8 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.

Applicants should amend the claims to reflect the elected invention (i.e., Applicants should amend the claims to reflect only SEQ ID NOS: 4 and 23, and amend Claim 5 to only depend from Claim 3).

Sequence Notes

3. The Sequence Listing filed in this application complies with the requirements of 37 CFR 1.821-1.825 and has been entered.

Information Disclosure Statement

4. The information disclosure statements filed on May 2, 2002 and August 2, 2002, comply with 37 CFR 1.97, 1.98, and M.P.E.P. 609, and have been considered (see enclosed, signed PTO-1449). However, it is noted that reference AO (JP 2650159), submitted in the May 2, 2002 information disclosure statement has not been considered, since there is no English translation, nor is there a concise explanation of the relevance of this document. See 37 CFR 1.98(a)(3).

Specification

5. The disclosure is objected to because pages 3-5, recite "the invention according to claim ...", which is objected to, as the specification cannot refer to a claim within the instant application, as the claim number may change during the prosecution of the application.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claims 3 and 5-7 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

A) Claims 3 and 5-7 are indefinite because it is not clear as to method steps are required by the claims. The Claims do not recite positive, active method steps. See *Ex parte Erlich*, 3 USPQ2d 1011 (Bd. Pat. App. & Inter. 1986). Therefore, it is suggested that the claims be rewritten such that they set forth defined methods, such as by reciting "[a] process of amplifying Salmonella gene *invA* mRNA, comprising the steps of ...", after which a series of active steps is recited, for example "obtaining a sample containing Salmonella gene *invA* mRNA…", "amplifying…", etc.

B) Claims over 3 and 5-7 are indefinite over "the RNA" and "the formed RNA/DNA hybrid" because these recitations lack antecedent basis, because the claims do not previous recite "RNA" or "RNA/DNA".

C) Claims 3 and 5-7 over "specifically binding to" because it is not clear as to what is encompassed by this recitation. For example, it is not clear if the oligonucleotide only binds to the specific sequence required by the Claims (e.g., Salmonella gene *invA*, the RNA transcription product), and no other sequences, or it binds with a greater degree of complementarity to these sequences (e.g., Salmonella gene *invA*, the RNA transcription product), as compared to other

sequences, etc. The specification does not define the recitation of "specifically binding to", and therefore, the metes and bounds of this recitation are unclear.

D) Claims 3 and 5-7 because it is not clear when the oligonucleotides of SEQ ID NO: 4 and 23 are employed in the claimed methods. That is, the claim recites, "the amplification process being characterized by employing a first oligonucleotide...and a second oligonucleotide", however, the claim does not specify how the process is "characterized" by employing a first or second oligonucleotide.

Conclusion

8. No Claims are allowable. However, the prior art does not teach or suggest carrying out the process of amplifying Salmonella toxin gene invA mRNA using the primer pair of SEQ ID NO: 4 and 23.

9. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

The prior art of Simpkins et al. (Letters In Applied Microbiology (2000) 30: 75-79, cited in the IDS), Simpkins et al. (Journal of Microbiological Methods (1999) 38(3): 218), and Johansen et al. (Abstracts of the General Meeting of the American Society for Microbiology (2001) 101: 576) teach methods of performing NASBA of Salmonella. However, these references do not teach methods of performing NASBA using SEQ ID NOS: 4 and 23.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Alexander H. Spiegler whose telephone number is (571) 272-0788. The examiner can normally be reached on Monday through Friday, 7:00 AM to 3:30 PM.

If attempts to reach the examiner are unsuccessful, the examiner's supervisor, Gary Benzion can be reached at (571) 272-0782.

Papers related to this application may be faxed to Group 1637 via the PTO Fax Center using the fax number (703) 872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Alexander H. Spiegler
June 14, 2004

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6/14/04